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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,982	03/11/2004	Ganapati R. Mauze	10010186-3	6847

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,982

Applicant(s)

MAUZE ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Attention is directed to the header used in the response filed by applicant's representative, received via facsimile transmission 16 December 2004. It is noted with particularity that the application identified in the header is 10/798,892, while the instant application has Serial No. 10/798,982.

Priority

2. This application repeats a substantial portion of prior Application No. 09/848,869, filed 04 May 2001, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Response to argument

3. At page 6 of the response received 16 December 2004, hereinafter the response, applicant's representative asserts that a proper claim for benefit of priority was made on the Application data Sheet (ADS), and that as provided for under MPEP 601.05, no further act is required of applicant.

4. The above argument has been fully considered and has not been found persuasive. It is noted with particularity that the ADS claims that the instant application is a "continuation" of the

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'869 application. In order to be a continuation, both applications must be filed with the same specification and claims. Such is not the case here. Accordingly, the claim for benefit of priority as a continuation is denied. Applicant is again urged to consider a claim of priority where the instant application is a continuation-in-part of said '869 application.

Specification

5. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

All patents and publications mentioned herein, both *supra* and *infra*, are hereby incorporated by reference.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents.

Attention is also directed to MPEP 608.01(p)I, which, in pertinent part, is reproduced below:

Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. (Emphasis added)

As set forth In *Ex parte* Raible, 8 USPQ2d 1707, (BPAI, 1998)

The examiner is of the opinion that the general incorporation by reference of the Bentley disclosure in appellant's specification is insufficient to support the specific disputed limitations of the present claims in the manner required by section 112 of the statute. We agree

* * *

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We believe that the doctrine of incorporation by reference is of no avail to appellant in this regard since there is no specific indication in the instant specification of the particular features disclosed by Bentley which correspond to those intended for use in the here-claimed device; nor does the specification identify the specific portions of the patent which appellant may have intended to rely upon to supplement his disclosure. The purpose of incorporation by reference in an application of matter elsewhere written down is for economy, amplification, or clarity of exposition, by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144, (CCPA 1973).

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Response to argument

6. At page 5, bridging to page 6 of the response applicant's representative asserts that the issues in the cited cases are non-analogous to the present case, and asserts that the incorporations by reference meet the requirements of MPEP 608.01(p).

7. The above argument has been fully considered and has not been found persuasive. It is noted with particularity that no factual underpinning is offered as to how the one line found at the end of the specification, *supra*, provides any particular direction as to just which portion(s) of the cited documents the incorporated material may be found. Attention is directed to MPEP 2145.

Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.

The arguments of counsel cannot take the place of evidence in the record. In *re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In *re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). See MPEP § 716.01(c) for examples of

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attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

8. For the above reasons, and in the absence of convincing evidence to the contrary, the objection to the specification is maintained.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 22-29, 31, 33-37, 39, and 41 remain rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,952,172 (Meade et al.).

11. For convenience, claims 22, 26, and 34, the only independent claims, are reproduced below.

22. (Currently amended) A method comprising:
adding contacting a metal ion to an initial complex comprising a target and a probe labeled with a transition metal ligand complex to produce an electrically conductive complex;
and,
applying a potential to the electrically conductive complex to produce a detectable signal.

26. (Currently amended) A method comprising:
maintaining a composition comprising a target and a probe labeled with a transition metal ligand complex under conditions suitable for producing target/probe complexes;
doping contacting said composition with a metal ion to form a doped composition; and,
applying a potential to said doped composition in order to produce a detectable signal from any target/probe complexes produced.

34. (Previously presented) A method comprising:
hybridizing a target and a probe labeled with a transition metal ligand complex to form a first complex;
contacting said first complex with a metal ion to form an electrically conductive second complex; and,
applying a potential to said electrically conductive complex to produce a detectable signal.

12. For purposes of examination, the “metal ion” that is to be added to the “initial complex” has been construed as encompassing both metal ions free in solution as well as metal ions that are bound to some other molecule, yet are not part of the “initial complex.”

13. Meade et al., teach at length a method of detecting nucleic acids whereby transition metal-ligand complexes are attached to a probe that in turn hybridizes to a target nucleic acid. At column 7, an extensive list of both suitable transition metals and their ligands is provided.

14. Column 7, fourth paragraph, teaches that nickel, zinc, cobalt (claim 25), as well as ruthenium, osmium, and iridium can be used.

15. Column 7, lines 52-53, teach that ruthenium and osmium are particularly preferred (limitations of claims 24, 28, and 36). At column 8, bridging to column 9, Meade et al.,

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discloses use of an electrode or electrical potential so to cause the transition metal-ligand complex to emit light that is in turn detected.

16. Meade et al., column 14, second paragraph, teaches using primers (probes) that contain one member of an electron donor/acceptor pair, which hybridizes to a target sequence. The complex is further contacted with nucleotides that comprise the other member of the electron donor/acceptor pair. Meade et al., describe the nucleic acids that have both electron donor and acceptor bound thereto as 'molecular wire,' as an electrical current can flow. Such disclosure meets the limitation that an electrical potential is applied.

17. Meade et al., column 10, bridging to column 11, teaches immobilization Of nucleic acid probes to the surface of various solid supports. Such meets a limitation of claims 30, 32, 38, and 40.

18. For the above reasons, and in the absence of convincing evidence to the contrary, claims 22-29, 31, 33-37, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,952,172 (Meade et al.).

Response to argument

19. At pages 6-7 of the response applicant's representative asserts that Meade et al., do not teach contacting a metal-containing compounds with a probe/target complex labeled with a transition metal ligand complex.

20. The above argument has been fully considered and has not been found persuasive for as shown above, Meade et al., clearly contemplates using transition metals as a label on probes/primers, and that at column 14, labeled primers/probes are hybridized to a target nucleic acid so to form an initial complex, and are subsequently contacted with a metal-containing

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compound (nucleotide) that effectively serves as a doping step. Therefore, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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24. Claims 31, 33, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,952,172 (Meade et al.) in view of US Patent 6,027,889 (Barany et al.).

25. See above for the basis of the rejection as it relates to the disclosure of Meade et al.

26. While Meade et al., teach explicitly of coupling of probes to a solid support, they do not teach arranging the probes in an array.

27. Barany et al., Figure 1, depicts an addressable array of probes and captured target molecules.

28. In view of the detailed teachings of Meade et al., and Barany et al., one would have been motivated to have arranged the probes in an addressable array as such is an obvious design choice recognized and used in related art at time of filing.

29. For the above reasons, and in absence of convincing evidence to contrary, claims 31, 33, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,952,172 (Meade et al.) in view of US Patent 6,027,889 (Barany et al.).

Response to argument

30. At page 8 of the response applicant's representative asserts that the obviousness rejection cannot be maintained as Meade et al., does not anticipate the claimed invention. This argument has not been found persuasive towards the withdrawal of the rejection for as shown above, Meade et al., does in fact teach the alleged missing elements of the claimed invention, and as such, is available to use in the rejection under 35 USC 103(a).

31. Therefore, and in the absence of convincing evidence to the contrary, the rejection of claims 31, 33, 39, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,952,172 (Meade et al.) in view of US Patent 6,027,889 (Barany et al.) is maintained.

Double Patenting

32. Claims 22-41 of this application conflict with claims 7, 9-14, 16, 18-20, and 22-24 of Application No. 09/848,869. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

33. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

34. Claims 22-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 9, 10, 13-14, 16, 18-19, and 23 of copending Application No. 09/848,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method whereby a first complex is formed wherein said complex comprises a target and a probe labeled with a transition metal, and contacting/adding a metal ion to said initial complex to

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produce an electrically conductive complex, and applying a potential to the electrically conductive complex to produce a detectable signal.

35. Claims 9 and 10 of the '869 application corresponds to claims 24 and 25 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "B. L. Sisson".

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
15 February 2005